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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/294,980**

Applicant(s)  
**Dolly et al**

Examiner  
**Robert C. Hayes**

Group Art Unit  
**1647**



Responsive to communication(s) filed on \_\_\_\_\_

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 1-24 \_\_\_\_\_ is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) \_\_\_\_\_ is/are rejected.
- ☒ Claim(s) 24 \_\_\_\_\_ is/are objected to.
- ☒ Claims 1-24 \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some\* ☐ None ☐ of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1647

### **DETAILED ACTION**

1. Claim 24 is objected to because of the following informalities: The final claim (i.e., #24) is not numbered. Appropriate correction is required.

### ***Election/Restriction***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-5 & 10, drawn to methods for extending the effective time period time tissue is paralyzed with a clostridial toxin comprising administering a binding protein agent/competitive inhibitor that prevents the regenerative activity of various neurotrophic factors, classified in Class 514, subclass 2.
  - II. Claims 1-8, drawn to methods for extending the effective time period time tissue is paralyzed with a clostridial toxin comprising administering an antibody agent/competitive inhibitor that binds various neurotrophic factors, classified in Class 424, subclass 130.1.
  - III. Claims 1-6, 9, 11 & 13-24, drawn to methods for extending the effective time period time tissue is paralyzed with a clostridial toxin comprising administering agents that prevent the expression of various neurotrophic factors genes, including use of ribozymes, classified in Class 514, subclass 44.
  - IV. Claim 12, drawn to a method for stimulating the outgrowth of neural sprouts from damaged neural tissue comprising contacting the tissue with a composition

Art Unit: 1647

comprising active domains of various neurotrophic factors, classified in Class 514, subclass 12.

3. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patently distinct inventions for the following reason:

Groups I-IV are directed to methods of treating tissue with polypeptides, antibodies and agents involved in gene therapy. Each of these methods require physically and functionally distinct elements. For example, the use of polypeptide agents in the methods of Groups I and IV interact with entirely different types of molecules than the nucleic acid molecules/ribozymes required in the method of Group III, and vice versa. The method of Group II also requires use of antibodies that are physically and functionally distinct from the polypeptides used in the methods of Groups I and IV, or the nucleic acid agents used in the method of Group III, and vice versa. The method of Group IV further requires neural sprouts from damaged neural tissue to treat with specific domains of neurotrophic agents, which are not required in the methods of Group I-III: whereas the methods of Groups I-III require use of clostridial toxin that is not required in the method of Group IV, and vice versa. These inventions are, therefore, patentably distinct, since each method possesses its own unique materials and goals.

Art Unit: 1647

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*RC*  
Robert C. Hayes, Ph.D.  
September 11, 2000

*Patricia D. [Signature]*  
PATRICIA D. [Signature]  
[Signature]